**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 13, 2021

**MEMORANDUM**:

SUBJECT: Review of the Submission for a Section 18 Public Health Exemption by the Vermont Agency of Agriculture, Food and Markets for Use of Grignard Pure to Treat Indoor Air against SARS-CoV-2

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**Purpose**

Per your request, BEAD's Microbiology Laboratory Branch (MLB) conducted a technical review of the initial submission by the Vermont Agency of Agriculture, Food and Markets for a FIFRA Section 18 Public Health Emergency Exemption (see Data Package Bean Sheet Submission #1058052, Decision #566563, dated September 11, 2020) for the use of Grignard Pure to reduce the spread of SARS-CoV-2 in indoor facilities. Although the initial Vermont application was withdrawn, the technical review is applicable to requests from other states (Tennessee, Georgia) seeking a comparable emergency use of Grignard Pure. Triethylene glycol (TEG) is the active ingredient of the technology. The supplied materials were reviewed for

documented evidence, justification, and appropriateness to support a public health emergency and how, if approved, the use of Grignard Pure could help resolve the emergency and protect public health. If additional use sites, application practices or other substantive changes to the labelling are requested by other states, then MLB will amend the review to address those specific situations. The OPP Antimicrobials Division will conduct a review of the efficacy data provided by the applicant.

**Overview of the Request**

The Vermont Agency of Agriculture, Food and Markets (Vermont) initially requested a FIFRA Section 18 Public Health Emergency Exemption for the use of Grignard Pure to treat indoor air contaminated or potentially contaminated with aerosolized SARS-CoV-2, the causal agent of COVID-19. The request is for treating air in indoor use sites such as clinical environments, indoor entertainment and social congregation areas, public areas and other enclosed areas.

- The justification for a public health emergency exemption is based on the concept that the *primary* route of transmission of SARS-CoV-2 between people is through contact with respiratory droplets produced when talking, coughing or sneezing while people are within six feet of each other. Infections can occur via exposure to the virus in small droplets and particles that can linger in the air for minutes to hours. Furthermore, the virus particles may infect people who are further than 6 feet away from the person who is infected or after that person has left the space – this type of spread is referred to as *airborne transmission* and is an important way that infections like tuberculosis, measles, and chicken pox are spread.
    - Thus, the applicant believes that the treatment of air with an antimicrobial technology such as Grignard Pure will mitigate the risk of airborne transmission.
    - The applicant indicates Grignard Pure would be used as another "tool in the toolbox" and not a substitute for other measures recommended by public heath officials.
- Grignard Pure is not an EPA-registered product, and thus does not currently have EPA approval for sale or distribution under FIFRA as an antimicrobial product in the United States. The manufacturer, Grignard Company, LLC, is aware of the intent to potentially deploy the technology per the provisions described in the application. A draft label was provided for review (the label has been amended several times).
    - The active component of the formulation is TEG. The applicant cites the presumed efficacy of the TEG when delivered using fog/haze machines through an HVAC system or by placing machines in the enclosed space to be treated.
    - Grignard Pure represents a new type of proposed antimicrobial technology with a presumed airborne viricidal property and is expected to control SARS-CoV-2 in use patterns and locations not treatable by standard surface disinfectants identified

on EPA's List N - Disinfectants for Use Against SARS-CoV-2[1]. According to the application, Grignard Pure is capable of contacting, binding to, and inactivating airborne virus particles. EPA's List N products do not include approved antimicrobial products for inactivating airborne particles of the SARS-CoV-2, and EPA's List N products are intended to disinfect SARS CoV-2 on hard, non-porous surfaces. Thus, according to Vermont, EPA's List N products are ineffective against what is believed to be the more likely path for disease transmission of SARS-CoV-2, and current disinfecting methods are not scalable nor effective on large commercial or public areas that require frequent or continuous disinfecting without the ability to remove people from the treated area.

- According to Vermont, non-pesticidal means of control of SARS-CoV-2 (e.g., social distancing, masking, hand washing, ventilation) are inadequate or unfeasible. This position is based on the lack of consistent use and adherence of the guidelines and that the practices are not practical in all cases and are not entirely effective when implemented.

**Technical Review**

The Emergency.

- The ongoing SARS-CoV-2 pandemic is an emergency in the United States. As part of the Federal Government's efforts to minimize risks to its citizens, the EPA released List N (Disinfectants for Use Against SARS-CoV-2) and expedited the review of disinfectants for use against human coronavirus through the Emerging Viral Pathogens policy and PRIA process to provide additional products.
    - Currently, EPA List N does not include antimicrobial products intended to treat airborne virus. Thus, if approved and determined to be safe and effective, a technology such as Grignard Pure may be useful in mitigating the spread of SARS-CoV-2 in indoor settings when used according to the label.
- Based on CDC's current understanding, SARS-CoV-2 is most commonly spread through airborne respiratory droplets during close contact with an infected individual. That is, people who are physically near (within 6 feet) a person with SARS CoV-2 or have direct contact with that person are at greatest risk of infection and that some infections can be spread by exposure to virus in small droplets and particles that can linger in the air for minutes to hours (i.e., airborne transmission)[2]. Thus, use of recommended practices and engineering controls, approved and safe antimicrobial technologies, or a combination of

[1] https://www.epa.gov/pesticide-registration/list-n-disinfectants-coronavirus-covid-19
[2] https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html

approaches designed to reduce airborne transfer would be useful tools in the "toolbox" for mitigating the risk of infection.

- MLB recognizes that respiratory droplets can also land on surfaces and objects. According to the CDC, it is possible that a person could get SARS CoV-2 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or eyes; however, spread from touching surfaces is not thought to be a common way that SARS CoV-2 spreads.
- Multiple SARS-CoV-2 variants are circulating globally. In the United Kingdom, a new variant has emerged with an unusually large number of mutations. This variant seems to spread more easily and quickly than other variants. The variant has recently been identified in parts of the United States.

Alternative Practices.

- No pesticides are currently registered for the treatment of air against airborne particles of SARS-CoV-2. EPA List N products are labelled for treating contaminated surfaces.
- Detailed federal guidelines are in place to mitigate the risk of airborne exposure to SARS-CoV-2 and will aid in allowing businesses and establishments to safely open and sustain business. These recommendations should be considered as alternative practices prior to the use of an approved air treatment technology. The public health recommendations may be complimented with additional approved safe and effective tools such as Grignard Pure if warranted. Relevant federal guidelines include:
    a. Prevent Getting Sick[3]
    b. How to Protect Yourself & Others[4]
    c. Guidance for Cleaning and Disinfecting[5]
- The CDC also provides specific practices to manage the ventilation and filtration systems which provide heating, ventilating, and air-conditioning (HVAC systems) and how good management of these systems can reduce the airborne concentration of SARS-CoV-2[6].
    a. These recommendations should be considered as alternative means to reduce risk of exposure prior to or in conjunction with applying an air treatment technology such as Grignard Pure.
- For example, the following information is provided by the CDC to optimize the functioning of HVAC systems:
    a. Check to be sure your HVAC filter is correctly in place and consider upgrading the filter to the highest-rated filter that your system can accommodate.

[3] https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html
[4] https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html
[5] https://www.cdc.gov/coronavirus/2019-ncov/community/pdf/Reopening_America_Guidance.pdf
[6] https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/disinfecting-your-home.html#ventilation

b. HVAC systems only filter the air when the fan is running, so run the system fan for longer times, or continuously. Many systems can be set to run the fan even when no heating or cooling is taking place.
c. When used properly, air purifiers can help reduce airborne contaminants, including viruses, in a home or confined space.
d. Improve ventilation with outside air to improve indoor air quality (i.e., open the windows, or screened doors, if possible).
e. Operate a window air conditioner that has an outdoor air intake or vent, with the vent open.
f. Open the outside air intake of the HVAC system, if the system yours has one (this is not common).
g. Operate a bathroom fan when the bathroom is in use or continuously, if possible.
h. Running your HVAC system, using an air purifier or a portable air cleaner, and increasing ventilation are not enough to protect yourself and your family from SARS CoV-2. Continue to follow other prevention guidelines.

- Under the federal government's Operation Warp Speed, two vaccines are currently authorized and recommended to prevent COVID-19 in the United States. To help guide decisions about how to distribute limited initial supplies of COVID-19 vaccine, CDC and the Advisory Committee on Immunization Practices have published recommendations for which groups of people should be vaccinated first. The goal is for everyone to be able to receive a COVID-19 vaccine as soon as sufficient quantities are available. Supplies are expected to increase over time. Based on what is known about vaccines for other diseases and early data from clinical trials against SARS-CoV-2, experts believe that getting a COVID-19 vaccine will make it substantially less likely you'll get COVID-19 and may also keep people from getting seriously ill from the virus. CDC's website on the COVID-19 vaccines is a useful resource[7].

Proposed Use.

- A draft label (GRIGNARD PURE Antimicrobial Air Treatment) and user manual (Amhaze Stadium) were provided by the applicant and reviewed for technical content. The label was amended several times with input from MLB. Grignard Pure is for indoor use only (occupied and unoccupied) and the labelling indicates the product inactivates 98% of airborne viruses. The proposed label provides use directions on machine setup and implementation through HVAC integration or the use of portable devices placed in

[7] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

strategic locations; these are water-based vaporizing units (certified by the company). The proposed application of Grignard Pure is for up to 12 hours of continuous application for a maximum of 12 hours per a 24-hour period. An airborne concentration of 0.5mg/$m^3$ to 2mg/$m^3$, corresponding to a visible light haze to a moderate haze, respectively, is provided. The amount of product needed to treat an enclosed space depends on the volume of the treated space, air exchange rate, and hours of operation. Wall-mounted sensors or visual observation of haze are used to determine product concentration.

- The draft Grignard Pure label (initial version) claims 98% inactivation of numerous airborne viruses and bacteria – the label should only present instructions for treating the target microbial agent (human coronavirus) if approved under a Section 18 exemption.
    - Note: the stated 98% reduction is relatively low and does not meet agency proposed guidance for air sanitizers of 99.9% reduction.
- The draft Grignard Pure label indicates use of a visual observation (an option) of the degree of haze (i.e., light to moderate level) for verifying the concentration of the product during its continuous use.

**Conclusions and Recommendations**

- The SARS-CoV-2 pandemic is an ongoing non-routine emergency in the United States. SARS-CoV-2 is most commonly spread through airborne respiratory droplets during close contact with an infected individual. Air treatment technologies such as Grignard Pure, if shown to be efficacious and safe, may in theory be useful tools in reducing the spread and persistence of airborne SARS-CoV-2 in indoor spaces especially under certain circumstances where risk mitigation recommendations are difficult to implement.
- COVID-19 vaccines currently available in the United States have been shown to be highly effective (i.e., in clinical studies) at preventing COVID-19; however, it will take time for supplies of the vaccines to be generated and to perform the vaccinations to increase immunity.
- MLB recommends that the option (on the draft label) for visually assessing the density of the haze be removed or modified (add training materials) to provide clarity and demonstration of the assay.
    - If retained, training materials and further instructions on this approach should be provided to the end-users.
- MLB recommends the label should clearly instruct users to follow the Federal, State and local public health guidelines pertaining to mitigating risk of spreading and acquiring SARS CoV-2; these practices, including the management of ventilation, should be used in conjunction with Grignard Pure. For example:

    "*Follow SARS-CoV-2 risk mitigation guidelines issued by Federal, State and local public health officials. Grignard Pure is not to be relied upon as a sole*

*mitigation but is a supplemental treatment to be used in conjunction with current public health guidelines."*

- The label should indicate conditions (triggers for use of the product) where the deployment of the public health guidelines to reduce airborne transmission is deemed problematic (e.g., high occupancy environments, lack of social distancing, poor ventilation). For example:

  "*For use in indoor spaces (occupied or unoccupied) when adherence to current public health guidelines (social distancing, limited occupancy, and increased ventilation) is impractical, difficult to maintain, or is not expected to provide a sufficient level of protection.*

- MLB recommends labelling of only human coronavirus as the target pest.
- The application of an antimicrobial product in the air such as Grignard Pure represents a use pattern that is substantially different from hard surface disinfectants or sanitizers, and an approved test method and performance standard for use in assessing product efficacy have not been developed. MLB supports efforts by the federal government and stakeholders to develop methodologies to make such claims.
  - For background purposes, see OCSPP 810.2500: Air Sanitizers – Efficacy Data Recommendations; this guideline addresses efficacy testing for antimicrobial pesticides intended to be used for the treatment of air to temporarily reduce the number of airborne bacteria.
  - The performance claim of 98% inactivation does not meet the proposed performance level of air sanitizers (99.9%) and thus may reduce its practical value in protecting the public against SARS-CoV-2.

Please contact Stephen Tomasino at 410-305-2976 if you have any questions or comments regarding this review.

cc: Kristen Willis, Tajah Blackburn